IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

First Named Inventor:	JAPUNTICH, DANIEL A.		
Application No.:	09/678580	Confirmation No.:	7366
Filed:	October 3, 2000	Group Art Unit	3743
Title:	FIBROUS FILTRATION FACE MASK HAVING A NEW UNIDIRECTIONAL FLUID VALVE		

BRIEF ON APPEAL

Mail Stop: Appeal Brief-Patents
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Sir:

This is an appeal from the Office Action mailed on August 24, 2006, finally rejecting claims 34-58 and 60-87.

Any required fee will be paid at the time of EFS-Web submission.

If necessary, charge any required fee, or credit any overpayment to Deposit Account No. 13-3723.

A Notice of Appeal in this application was submitted on November 14, 2006, and was received in the USPTO on November 14, 2006.

Appellants request the opportunity for a personal appearance before the Board of Appeals to argue the issues of this appeal. The fee for the personal appearance will be timely paid upon receipt of the Examiner's Answer.

REAL PARTY IN INTEREST

The real party in interest is 3M Company (formerly known as Minnesota Mining and Manufacturing Company) of St. Paul, Minnesota and its affiliate 3M Innovative Properties Company of St. Paul, Minnesota.

RELATED APPEALS AND INTERFERENCES

A Notice of Appeal has been filed in U.S. Serial No. 09/680,465 on December 5, 2006.

STATUS OF CLAIMS

Claims 34-58 and 60-87 are pending and are the subject of this appeal.

STATUS OF AMENDMENTS

No amendments have been filed after the final rejection.

SUMMARY OF CLAIMED SUBJECT MATTER

The present invention pertains to a filtering face mask 10 that comprises:

a mask body 12 and an exhalation valve 14:

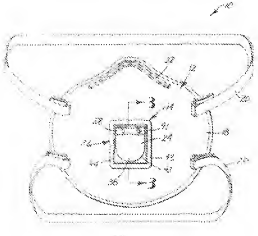


Fig 1

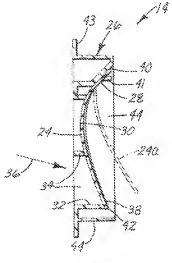


Fig 3

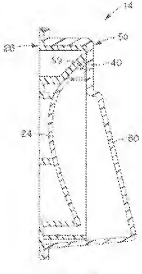


Fig 11

The mask body 10 is adapted to fit over the nose and mouth of a wearer, and the valve 14 is attached to the mask body 10. The exhalation valve 14 comprises a valve seat 26 that includes: (i) a seal surface 31; (ii) an orifice 32 that is surrounded by the seal surface 31 (FIG. 4); and (iii) a flap-retaining surface 40. The exhalation valve 14 also has a single flexible flap 24 that has a stationary portion 28 and only one free portion and a peripheral edge that extends 360° about the flap 24. See specification at page 6, lines 25-34, page 7, lines 15-26, and pages 11, lines 22-30. The peripheral edge includes a stationary segment and a free segment. The stationary segment is associated with the stationary portion 28 of the flap 24 so as to remain at rest during an exhalation, and the free segment is associated with the free portion of the flexible flap 24 so as to be lifted away from the seal surface 31 during an exhalation (page 7, lines 20-22; page 11, lines 8-11). The free segment is also located below the stationary segment when the filtering face mask is worn on a person and viewed from the front (FIG. 1) (page 11, lines 27-30). A valve cover 50 that is disposed over the valve seat 26 and comprises a surface 59 that holds the flexible flap against the flap-retaining surface 40 in a location and position relative to the seal surface 31 such that the flap 24 is pressed towards the seal surface 31 in an abutting relationship therewith when a fluid is not passing through the orifice 32 under any orientation of the valve 14 (page 9, lines 14-16, page 14, liens 35-37, page 15, lines 14-16). The point where the flexible flap 24 is mechanically held against the flap retaining surface 40 is located off center relative to the flap 24 (Figs. 1, 3, and 8).

Applicants discovered that an exhalation valve having this construction is beneficial in that it can provide a low airflow resistance during an exhalation and can remain pressed towards the seal surface under any orientation of the valve. Prior cantilevered valve structures such as those show in GB 2, 072,516 to Simpson were subject to leakage when a wearer tipped their head downward. See Simpson at page 1, lines 58-64. Other prior art respirators have used dual-flap systems, such as those disclosed in U.S. Patent 4,934,362 to Braun (see also, U.S. Patent 2,105,183 to Cover), which exhibit higher air flow resistance forces since the moment arm is shorter and the mounting hardware obstructs airflow through the valve (see Examples 4-6 as set forth in applicants' specification).

When a person wears a filtering face mask that has an exhalation valve, the wearer's lungs are responsible for providing the power to open and close the exhalation valve. When the valve exhibits a higher airflow resistance force, more power is needed to operate the valve while the

mask is being donned. If the exhalation valve requires more power to operate, the wearer must breath harder throughout the working day. Filtering face masks that use valves that have higher airflow resistance forces therefore can become uncomfortable to wear over extended periods of time. A mask that has improved comfort, however, is less likely to be removed from the wearer's face during use and therefore provides enhanced safety. Applicants' invention is an improvement over centrally-mounted valves such as button valves and the dual-flap systems disclosed in Braun and Cover.

GROUNDS OF REJECTION TO BE REVIEWED ON APPEAL

First Ground of Rejection

Claims 68, 34-36, 50-56, 58, 60-75, and 76-82 have been rejected under 35 USC § 103(a) as being unpatentable over the combined teachings of UK Patent Application GB 2,072,516 to Simpson, in view of European Patent Application 0252890 to Söderberg, and US Patent 1,701,277 to Shindel.

Second Ground of Rejection

Claims 37-49 and 83-87 have been rejected under 35 USC § 103(a) as being unpatentable over the combined teachings of Simpson, Söderberg, and Shindel and further in view of U.S. Patent 2,105,183 to Cover.

ARGUMENT

First Ground of Rejection

None of the references relied on in the first ground of rejection teach or suggest holding the flexible flap against the flap-retaining surface in a location and position relative to the seal surface such that the flap is pressed towards the seal surface in a substantial abutting relationship therewith.

In applicants' invention, a valve cover 50 is disposed over the valve seat 26, and it 50 comprises a surface 59 that mechanically holds the flexible flap 24 against the flap-retaining surface 40. The flexible flap 24 is held against the flap-retaining surface 40 in a location and position relative to the seal surface 31 such that the flap 24 is pressed towards the seal surface 31 in a substantial abutting relationship therewith under any orientation of the valve 14 when a fluid is not passing through the orifice 32:

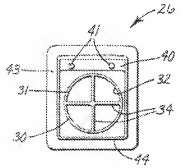


Fig 4

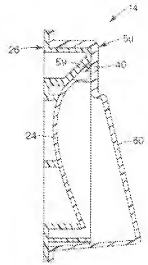


Fig 11

Applicants' Invention

Applicants' Invention

in both Simpson and Shindel, the flap-retaining surface is in direct alignment with the seal surface:

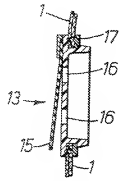


FIG. 2.

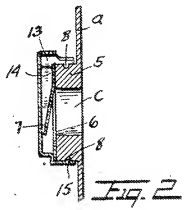


Fig. 2

Simpson

Shindel

As such, the flexible flap cannot be held in a location and position such that the flap is pressed towards the seal surface. These references therefore provide very good evidence of the nonobviousness of applicants' invention. Although Söderberg teaches a flexible flap that is purportedly pressed against the seal surface, Söderberg does not do this through use of a valve cover and a flap-retaining surface that is located and positioned relative to the seal surface such that

the flap is pressed towards the seal surface in an abutting relationship with it. Söderberg states that "the rubber material [of the flexible flap] is resilient and if the membrane is given a beveled edge, it will then seal against the border of the valve seat in a closed position...." Söderberg's valve remains closed as a result of the valve membrane material and its shape and not as the result of any valve cover or the positioning of the flap-retaining surface relative to the seal surface.

In responding to applicants' characterization of Söderberg, the Examiner states that "Söderberg (page 6, lines 1-3) discloses optional methods of attachment including clamping of the valve membrane to the seat." And that "Söderberg makes clear that the reason for sealing of the valve membrane to the valve seat lies in the combination of the manner of attachment (which is peripheral as disclosed on page 5, lines 22-29) and the beveled edge and not solely in the material of the valve membrane as argued by applicants." In reviewing this Appeal Brief, applicants urge the Examiner to reconsider applicants' above-stated argument. Applicants have not simply argued that Söderberg's flexible flap material is responsible for having the valve remain closed. Applicants' argument is essentially a restatement of what Söderberg specifically discloses, namely, that the rubber material and the beveled edge are responsible for keeping the valve in a closed position.

Applicants have also considered page 5, lines 22-29 and page 6, lines 1-3 of the Söderberg disclosure, which were cited by the Examiner in the Office Action. In neither of these locations, however, have applicants noticed that Söderberg teaches or suggests a structure whereby the flexible flap is held against the flap retaining surface in a location and position relative to the seal surface such that the flap is pressed towards the seal surface in a substantial abutting relationship therewith under any orientation of the valve. At that part of its disclosure, Söderberg is only describing comparative test results and is only indicating that the flap "might, for instance, be attached to the valve seat by moulding, clamping, etc...."

Söderberg shows a planned view of its valve construction and that plan view gives no hint as to the relationship between the flap-retaining surface and the seal surface:

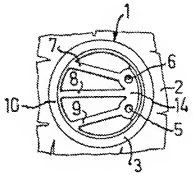


FIG. 1

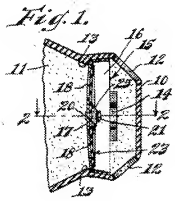
The flap-retaining surface could be located above the seal surface, below the seal surface, or in alignment with the seal surface as taught by Simpson and Shindel. Even if Söderberg's flap-retaining surface was located below the seal surface, its rubber material could possibly be thicker at the point of securement. Because Söderberg does not possess sufficient detail for a reader to come to a conclusion as to the particular location and positioning of the flap-retaining surface relative to the seal surface, it is not proper to speculate or conclude that Söderberg teaches or suggests a particular feature of applicants' invention. What we do know is that Söderberg teaches a very different structure for keeping the flap pressed towards the seal surface --- namely, a beveled edge on the flap. The fact that Söderberg takes this approach presents very good evidence of the nonobviousness of applicants' invention.

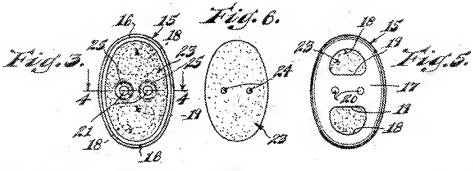
For the above reasons, applicants believe that the first ground of rejection under 35 USC § 103(a) cannot be properly sustained.

Second Ground of Rejection

The '183 patent to Cover has been additionally cited for suggesting a structure whereby the flap is curved and would "function more efficiently." The Examiner asserts that a person of ordinary skill would have combined the teachings of Cover with the other references because Cover's teachings "would have improved the closing action of the flap, improved the retention of the valve flap in effective registration with the apertures of the valve seat and cause the valve flap to function more efficiently." The combination of Cover with the other references, it is asserted, would have rendered applicants' invention obvious to a person of ordinary skill.

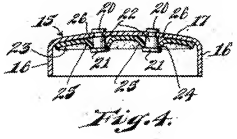
Cover discloses a valve that has the following construction:





In Cover, the valve has a frame 15 that is provided with a pair of stud pins 20 that are adapted to act as hinges for the movable valve element 23. The valve element 23 may be made of a thin sheet of flexible or resilient rubber material that has a pair of apertures 24 that register with the pins 20. Cover indicates that its pins 20 "are centrally located in the base plate 17 of the frame 15". See Cover, page 1, lines 53-55.

Cover's movable valve element or flap 23 has apertures 24 that are sized to be smaller than the reduced portions 22 of the stud pins 20. This enables the aperture forming walls 25 to seat in a cone-like manner about the reduced portions 22 of the pins 20:



In this manner, the walls 25 form pockets 26 between the portions of the flap that rest on the base plate 17. Cover states that "when the movable element 23 is placed in position, the curved

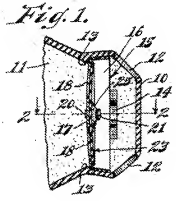
portions 25 will be under tension and will gently but firmly force the valve 23 to lie snugly upon the base plate 17 within the flange 16." See Cover at the sentence that bridges pages 1 and 2.

In claim 4, Cover states that the "pins form the sole means for distorting the adjacent portions of said valve element [23] to maintain the same in a concave shape as substantially as described." In claim 5, Cover further states that "the openings in the valve member [23] are of smaller diameter than that of said pins [20], as and for the purpose specified." Cover states that the pins 20 "may be slightly inclined towards each other as shown in Figures 2 and 4 to increase the snapping tension of the movable element."[1]

The combination of Simpson, Söderberg, Shindel, and Cover would not have rendered applicants' invention obvious to a person of ordinary skill for the following reasons.

Firstly, Cover does not suggest that its structure would improve the closing action of a cantilevered valve flap (like the valves disclosed in Simpson and Shindel). Cover also does not suggest that the combination of its teachings with Simpson and Shindel would have "caused the valve flap to function more efficiently." Only applicants' disclosure provides the structure and valve performance data to demonstrate that an improved cantilevered valve can be created that has the ability to deliver a low airflow resistance force, as well allowing the flap to be pressed towards the seal surface under any orientation of the respirator.

Cover discloses an exhalation valve that is centrally mounted through use of pins 20 and that has a dual-flap system for displacing exhaled air:



[1] See Cover at page 2, column 1, lines 54-56.

Another patent that uses a centrally-mounted, dual-flap system is U.S. Patent 4,934,362 to Braun:

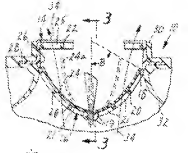


FIG. 2

In Examples 4-6 of applicants' specification, comparative performance data was generated with respect to applicants' invention (Example 4) and reproductions of Braun's working examples (Examples 5 and 6). The results of these tests are set forth in Table 1 of applicants' specification and are reproduced below for ease of reference:

TABLE 1

Example	*Orifice Area (cm^2)*	*Pressure Drop (Pascals)*	*Airflow Resistance Force (Newtons)*
4	5.3	26.46	0.0140
5*	5.3	60.76	0.0322
6*	13.5	17.64	0.0238

*Comparative examples corresponding to examples 2 and 4 of the '362 patent, respectively.

As the data indicates, applicants' invention exhibits far less airflow resistance force than that of Braun.[2] Although Braun is different from Cover in that it has a greater curvature to its valve seat, a person of ordinary skill could reasonably expect that applicants' invention would perform similarly superior to the valve disclosed in Cover because both Braun and Cover are dual-flap valve systems. Both Braun and Cover place their mounting hardware in a central location, which can interfere with the flow of air through the valve orifice. Cover does not provide any representation or expectation that its teachings could deliver better "closing action" or "improved

[2] Less airflow resistance is better because air can be purged more easily from the mask interior. The mask wearer does not need to supply as much energy to operate the valve.

efficiency" to a cantilevered exhalation valve. Cover only makes such representations with respect to its dual-flap exhalation valve.

Secondly, Cover does not indicate that the mounting hardware should be placed at one end of the flap. Cover also does not describe how to keep the flap closed if the mounting hardware is placed at one end. As late as 1987, the prior art, in fact, recognized that the placement of the mounting hardware at one end of a dual-flap system would create troubles in enabling the flap to remain closed under any orientation of the valve. For example, Braun states that "if the flap is too long, it might not have sufficient resilience to become quickly seated and to resist extraneous unseating forces."[3] Additionally, Braun indicates that a larger radius of curvature in a dual-flap system would tend to make the seal unreliable:

> A smaller radius of curvature would provide a better seal, but this would tend to make the seal ridge more expensive to manufacture. While a larger radius of curvature would be more economical, the seal may not be as reliable.[4]

As you can see by comparing Figure 2 of Braun with Figure 1 of Cover, Cover's valve seat has a much larger radius of curvature than the Braun valve seat. Thus, Braun demonstrates that persons of ordinary skill did not appreciate the fact that you could use a single flap system (as opposed to a dual-flap system) whereby the mounting hardware was disposed at one end of the flap and the orifice was located wholly below the flap and that you could achieve a reliable seal under any orientation of the flap.

Thirdly, Cover does not suggest applicants' claimed structure. In Cover, the flap is pressed against the seal surface by virtue of having apertures 24 smaller than the size of the cylindrical portion 22 of the pins 20. Cover states that the valve flap can seat in a "cone-like manner about the reduced portions 22 of the pins 20". Cover states that it is these curved portions 25 that are generated at the mounting pins 20 that are responsible for having the valve flap forced "to lie snugly upon the base plate 17".

Thus, Cover, like both Simpson and Söderberg also describes a different means for allowing the flexible flap to be pressed against the seal surface. Cover uses apertures 24 in the flexible flap that are smaller than the pins 20 to achieve a good seal. Cover does not suggest using a surface on a valve cover to hold the flap against a flap-retaining surface and to position that flap-

[3] See U.S. Patent 4,934,362 to Braun at column 3, lines 40-43.
[4] *Id.* at column 3, lines 6-10.

retaining surface relative to the seal surface to cause the flap to be pressed towards the seal surface in a substantial abutting relationship therewith under any orientation of the valve. If Cover were to move its seal surface towards one end of its valve such that its dual flap construction was converted to a seal single flap construction, there would be no guarantee that the resulting structure would be able to be pressed towards the seal surface in a substantial abutting relationship with it under any orientation of the valve. The Federal Circuit has stated that "[t]he consistent criterion for determination of obviousness" is whether the prior art would have suggested to one of ordinary skill in the art that the invention is suggested and "would have a reasonable **likelihood of success**, [when] viewed in light of the prior art."[5] The Federal Circuit has made clear that "[b]oth the suggestion and the expectation of success must be founded in the prior art, not in applicant's disclosure."[6] As the Braun disclosure makes clear, persons of ordinary skill would not have had any expectation that the movement of Cover's mounting hardware from the center of the valve led to one of the valve flap would have been expected to be successful in creating a reliable seal. The record therefore demonstrates that the prior art fails to suggest applicants' claimed structure and its likelihood of success.

Fourthly, the fact that Simpson and Söderberg, both of which were filed many years after Cover's 1938 publication, reveal that persons of ordinary skill in the exhalation valve art took entirely different approaches to deal with the problem of preventing leakage or inflow through the exhalation valve. Simpson described the use of an antechamber to prevent leakage of the valve.[7] Söderberg suggested the use of a beveled flap.[8] Because these patents were published many years after the publication of Cover's valve, and because no teachings of Cover were adopted by them, this provides very good evidence of the nonobviousness of applicants' invention.[9] Both Simpson and Söderberg had this opportunity but chose to apply different structures for dealing with the problem. Therefore, even if we assume that Cover suggests the concept of having the flexible flap held against the flap-retaining surface in a location and position relative to the seal surface such that the flap is pressed towards the seal surface in a substantial abutting relationship therewith under any

[5] *In re Dow Chemical*, 837 F.2d 469, 473, 5 USPQ2d 1529, 1531, (Fed. Cir. 1988).
[6] *Id.*
[7] See GB 2,072,516 to Simpson at page 1, lines 58-64.
[8] See EP 0,252,890, to Söderberg at page 4, lines 14-21 and page 5, lines 1-13.
[9] *In re Ehrreich*, 146 USPQ31, 37 (CCPA 1965) ("Thus over 40 years elapsed in this art prior to appellant's filing date without anyone suggesting so far as the art cited shows, a non-sag thoriated tungsten filament or any way of producing it.").

orientation of the valve, the persons of ordinary skill who have worked in this field clearly chose not to apply it in their subsequent developments. The fact that Simpson and Söderberg took entirely different approaches demonstrates the nonobviousness of applicants' invention. Further, the fact that Braun clearly states that the movement of the mounting hardware from the center towards the end would not provide a reliable seal, particularly when the radius of curvature is small, further establishes the nonobviousness of applicants' invention over the prior art.

Fifthly, the record reveals that before applicants' invention commercial manufactures of filtering face masks commonly used the button valves to displace exhaled air. An example of a button valve is shown in Figure 3 of Simpson:

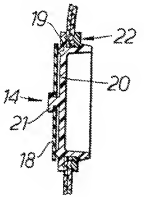
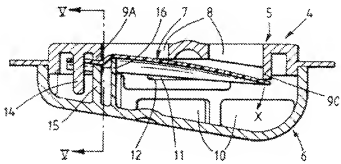


FIG. 3.

Applicants attach a copy of an Affidavit of Brian McGinley (Exhibit A), which indicates that it was not until after applicants' invention that cantilevered exhalation valves entered the market. The Board's attention is directed to the subsequent developments in U.S. Patent 5,687,767 to Bowers:

Fig.4.



Bowers

And U.S. Patent 6,047,698 to Magidson et al.:

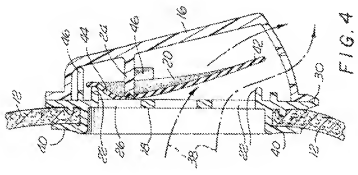
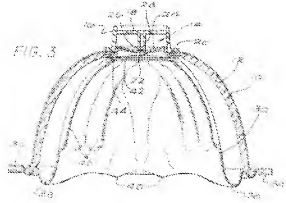


FIG. 4

Magidson et al.

Mr. John Bowers has stated that it was the publication of applicants' invention which spurred him into action.[10] Work done by Magidson (see U.S. Patent 4,873,972) before applicants' invention involved the use of button valves:



Accordingly, the state-of-the-art prior to applicants' invention does not reveal its obviousness, and the state-of-the-art after applicants' invention reveals how persons skilled in the art chose to follow applicants' teachings. The development of the valve art therefore provides yet further evidence of the nonobviousness of applicants' invention.

For the above reasons, applicants' submit that their invention would not have been obvious to a person of ordinary skill under the terms of 35 USC § 103.

[10] See paragraphs 8 and 9 of the John Bowers Declaration (Exhibit B).

CONCLUSION

For the foregoing reasons, appellants respectfully submit that the obviousness rejections cannot be properly sustained. Please reverse the decision below.

Respectfully submitted,

January 16, 2007
Date

By: 
Karl G. Hanson, Reg. No.: 32,900
Telephone No.: 651-736-7776

Office of Intellectual Property Counsel
3M Innovative Properties Company
Facsimile No.: 651-736-3833

CLAIMS APPENDIX

34. The filtering face mask of claim 68, wherein the valve seat is made from a relatively light-weight plastic that is molded into an integral one-piece body.

35. The filtering face mask of claim 34, wherein the valve seat has been made by an injection molding technique.

36. The filtering face mask of claim 68, wherein the seal surface is substantially uniformly smooth to insure that a good seal occurs between the single flexible flap and the seal surface, and wherein the flexible flap is made from a material that is capable of allowing the flap to display a bias towards the seal surface.

37. The filtering face mask of claim 68, wherein the flexible flap would normally assume a flat configuration when no forces are applied to it but has a curved profile when viewed from a side elevation.

38. The filtering face mask of claim 37, wherein the flexible flap is elastomeric and is resistant to permanent set and creep.

39. The filtering face mask of claim 37, wherein the flexible flap is made from an elastomeric rubber.

40. The filtering face mask of claim 68, wherein the flexible flap has a stress relaxation sufficient to keep the flexible flap in an abutting relationship to the seal surface under any static orientation for 24 hours at 70 °C.

41. The filtering face mask of claim 40, wherein the flexible flap provides a leak-free seal according to the standards set forth in 30 C.F.R. § 11.183-2, July 1, 1991.

42. The filtering face mask of claim 68, wherein the flexible flap is made from a crosslinked polyisoprene.

43. The filtering face mask of claim 68, wherein the flexible flap has a Shore A hardness of about 30 to 50.

44. The filtering face mask of claim 68, wherein the flexible flap has a generally uniform thickness of about 0.2 to 0.8 millimeters.

45. The filtering face mask of claim 44, wherein the flexible flap has a generally uniform thickness of about 0.3 to 0.6 millimeters.

46. The filtering face mask of claim 45, wherein the flexible flap has a generally uniform thickness of about 0.35 to 0.45 millimeters.

47. The filtering face mask of claim 68, wherein the one free portion of the flexible flap has a profile that comprises a curve when viewed from the front, which curve is cut to correspond to the general shape of the seal surface.

48. The filtering face mask of claim 47, wherein the flexible flap is greater than one centimeter wide.

49. The filtering face mask of claim 48, wherein the flexible flap is 1.2 to 3 centimeters wide and is about 1 to 4 centimeters long.

50. The filtering face mask of claim 68, wherein the stationary segment of the peripheral edge of the flexible flap includes about 10 to 25 percent of the total peripheral edge of the flexible flap, with the remaining 75 to 90 percent being free to be lifted from the seal surface.

51. The filtering face mask of claim 68, wherein the valve seat includes a flange that provides a surface onto which the exhalation valve can be secured to the mask body, and wherein the flange extends 360 degrees around the valve seat where the valve seat is mounted to the mask body.

52. The filtering face mask of claim 68, wherein the flexible flap is positioned on the valve such that exhaled air is deflected downward during an exhalation when the filtering face mask is worn on a person.

53. The filtering face mask of claim 68, wherein the mask body is cup-shaped and comprises (1) at least one shaping layer for providing structure to the mask, and (2) a filtration layer, the at least one shaping layer being located outside of the filtration layer on the mask body.

54. The filtering face mask of claim 68, wherein a high percentage of the exhaled air is purged through the exhalation valve.

55. The filtering face mask of claim 68, wherein at least 60 percent of the total airflow flows through the exhalation valve under a normal exhalation test.

56. The filtering face mask of claim 55, wherein at least 73 percent of the total airflow flows through the exhalation valve under a normal exhalation test.

58. The filtering face mask of claim 68, wherein the exhalation valve is positioned on the mask body substantially opposite to a wearer's mouth, and wherein the flexible flap is mounted to the valve seat in cantilever fashion.

60. The filtering face mask of claim 68, wherein the shape of the orifice does not wholly correspond to the shape of the seal surface.

61. The filtering face mask of claim 68, wherein the valve cover has an opening that is disposed directly in the path of fluid flow when the free portion of the flexible flap is lifted from the seal surface during an exhalation.

62. The filtering face mask of claim 61, wherein the opening in the valve cover is approximately parallel to the path traced by the second end of the flexible flap during its opening and closing.

63. The filtering face mask of claim 62, wherein the valve cover and its opening direct exhaled fluid flow downwards when the mask is worn on a person.

64. The filtering face mask of claim 63, wherein the valve cover has fluid-impermeable sidewalls.

65. The filtering face mask of claim 63, wherein the opening in the valve cover is at least the size of the orifice in the valve seat.

66. A filtering face mask that comprises:

(a) a mask body that is adapted to fit over the nose and mouth of a wearer; and

(b) an exhalation valve that is attached to the mask body, the exhalation valve comprising:

(1) a valve seat that comprises:

(i) a seal surface;

(ii) an orifice that is surrounded by the seal surface; and

(iii) a flap-retaining surface; and

(2) a single flexible flap that has a stationary portion and only one free portion and a peripheral edge that includes a stationary segment and a free segment, the stationary segment of the peripheral edge being associated with the stationary portion of the flap so as to remain at rest during an exhalation, and the free segment being associated with the one free portion of the flexible flap so as to be lifted away from the seal surface during an exhalation, the free segment also being located below the stationary segment when the filtering face mask is worn on a person and viewed from the front; and

(3) a valve cover that is disposed over the valve seat and that comprises a surface that mechanically holds the flexible flap against the flap-retaining surface, wherein the flexible flap is held against the flap-retaining surface in a location and position relative to the seal surface such that the flap is pressed towards the seal surface in a substantial abutting relationship therewith under any orientation of the valve when a fluid is not passing through the orifice.

67. The filtering face mask of claim 66, wherein the valve cover is secured to the valve seat by a friction fit to a wall of the valve seat.

68. A filtering face mask that comprises:

(a) a mask body that is adapted to fit over the nose and mouth of a wearer; and

(b) an exhalation valve that is attached to the mask body, the exhalation valve comprising:

(1) a valve seat that comprises:

(i) a seal surface;

(ii) an orifice that is surrounded by the seal surface; and

(iii) a flap-retaining surface; and

(2) a single flexible flap that has a stationary portion and only one free portion and a peripheral edge that extends 360° about the flap and that includes a stationary segment and a free segment, the stationary segment of the peripheral edge being associated with the stationary portion of the flap so as to remain at rest during an exhalation, and the free segment being associated with the one free portion of the flexible flap so as to be lifted away from the seal surface during an exhalation, the free segment also being located below the stationary segment when the filtering face mask is worn on a person and viewed from the front; and

(3) a valve cover that is disposed over the valve seat and that comprises a surface that holds the flexible flap against the flap-retaining surface in a location and position relative to the seal surface such that the flap is pressed towards the seal surface in an abutting relationship therewith when a fluid is not passing through the orifice under any orientation of the valve, the point where the flexible flap is mechanically held against the flap retaining surface being located off center relative to the flap.

69. The filtering face mask of claim 68, wherein the valve cover is secured to the valve seat by a friction fit to a wall of the valve seat.

70. The filtering face mask of claim 68, wherein the valve cover has fluid-impermeable opposing sidewalls that support a fluid impermeable ceiling, and wherein the valve cover has an opening that is disposed directly in the path of fluid flow, the fluid-impermeable sidewalls and the ceiling and the positioning of the opening in the valve cover causing fluid flow to be directed downwardly away from a wearer's eyes during an exhalation when the mask is worn by a person.

71. The filtering face mask of claim 70, wherein the flexible flap is mechanically clamped between the surface on the valve cover and the flap-retaining surface.

72. The filtering face mask of claim 68, wherein the flap-retaining surface is not disposed substantially in the path of the exhale flow stream.

73. The filtering face mask of claim 68, wherein the orifice includes a plurality of openings, which plurality of openings are disposed within the orifice beneath where the flexible flap is mounted to the valve seat when viewing the filtering face mask from the front in an upright position.

74. The filtering face mask of claim 73, wherein the exhaled air passes primarily through the plurality of openings within the orifice during an exhalation by a wearer of the mask.

75. The filtering face mask of claim 74, wherein the flap-retaining surface is located outside the region defined by the plurality of openings.

76. The filtering face mask of claim 66, wherein the flap-retaining surface is spaced from the nearest portion of the orifice at about 1 to 3.5 millimeters.

77. The filtering face mask of claim 66, wherein the flap-retaining surface is spaced from the nearest portion of the orifice at about 1.5 to 2.5 millimeters.

78. The filtering face mask of claim 66, wherein the flexible flap has a generally uniform thickness and is cut in the general shape of a rectangle such that the free segment of the peripheral edge corresponds to the shape of the seal surface where the free portion makes contact therewith.

79. The filtering face mask of claim 78, wherein the flexible flap is about 1.2 to 3 centimeters wide and is about 1 to 4 centimeters long and has a thickness of about 0.2 to 0.8 millimeters, and wherein the stationary segment of the peripheral edge is about 10 to 25% of the total peripheral edge and the free segment is about 75 to 95% of the peripheral edge.

80. The filtering facemask of claim 79, wherein the flexible flap is about 2.4 centimeters wide.

81. The filtering face mask of claim 66, wherein the valve cover is secured to the valve seat by ultrasonic welding or an adhesive and wherein the flexible flap is a sheet having a generally uniform thickness of about 0.3 to 0.6 millimeters.

82. The filtering face mask of claim 81, wherein the flexible flap has a generally uniform thickness of 0.35 to 0.45 millimeters.

83. The filtering face mask of claim 66, wherein the flexible flap is curved over the orifice.

84. The filtering face mask of claim 83, wherein the orifice includes a plurality of openings, which plurality of openings are disposed beneath where the flexible flap is mounted to the valve seat when viewing the filtering face mask from the front in an upright position.

85. The filtering face mask of claim 84, wherein the exhaled air passes primarily through the plurality of openings within the orifice during an exhalation by a wearer of the mask.

86. The filtering face mask of claim 85, wherein the flap-retaining surface is located outside the region defined by the plurality of openings.

87. The filtering face mask of claim 86, wherein the flap-retaining surface is spaced from the nearest portion of the orifice at about 1 to 3.5 millimeters.

EVIDENCE APPENDIX

Exhibit A

PATENT
Docket No.: 48317USA3C.014

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:	
DANIEL A. JAPUNTICH ET AL.	Group Art Unit: 3761
Serial No.: 08/240,877	
Filed: May 11, 1994	Examiner: A. Lewis
For: UNIDIRECTIONAL FLUID VALVE	

AFFIDAVIT OF BRIAN S. MCGINLEY

I, Brian S. McGinley, being duly sworn, state as follows

1. I presently hold the position of Product Marketing Manager in the Occupational Health & Environmental Safety Products Division (OH&ESD) at the 3M Company, St. Paul, Minnesota. In this position I am responsible for pricing, promotion, packaging, and positioning of 3M OH&ESD respiratory products.

2. I have been working in the respiratory field for the past 18 years and am very familiar with the art pertaining to personal respiratory protection devices, including filtering face masks that are worn over the nose and mouth of a person and that use exhalation valves to purge warm, moist exhaled air from the mask interior.

3. I am familiar with the subject matter of the above-captioned patent application, and I have reviewed the claims pending in this application and understand their scope and content.

4. I have witnessed the evolution of the art in respiratory products, in particular the evolution of the exhalation valve art on filtering face masks. On information and belief, I believe that the following sequence of events has occurred in this field:

a. Before May 29, 1992, 3M invented a filtering face mask that comprised a mask body and an exhalation valve. The mask body was adapted to fit over the nose and mouth of a person and had a filtering layer for filtering air that passed through the mask body.

The exhalation valve was attached to the mask body, and it comprised a valve seat that included an orifice, a seal surface surrounding the orifice, and a flap retaining surface. The exhalation valve also had a single flexible flap that had a stationary portion, one free portion, and a circumferential edge that included stationary and free segments. The stationary segment of the circumferential edge was associated with the stationary portion of the flexible flap so as to remain in substantially the same position during an exhalation, and the free segment of the circumferential edge was associated with the one free portion of the flexible flap so as to be movable during an exhalation. The free segment of the circumferential edge was disposed beneath the stationary segment when the valve is viewed from the front in an upright position.

This filtering face mask differed from known commercial products in that the flexible flap was noncentrally secured to the valve seat (relative to the orifice) at the flap retaining surface, and the flap retaining surface and seal surface were nonaligned and positioned relative to each other to allow for a cross-sectional curvature of the one free portion of the flexible flap when viewed from the side in a closed position. The nonalignment and relative positioning of the flap-retaining surface and the seal surface also allowed for the free portion of the flexible flap to be pressed towards the seal surface when a fluid was not passing through the orifice and to allow for the free portion of the flexible flap to be lifted from the seal surface during an exhalation.

b. On December 9, 1993, the filtering face mask described in paragraph 4.a was first published in International Publication WO 93/24181. This new filtering face mask was also published in U.S. Patent 5,325,892 on July 5, 1994.

c. In 1993, OH&ESD introduced in Europe its filtering face mask product that had a valve that included the structure described above in paragraph 4a. An Example of this kind of valve is attached to this Affidavit as Exhibit A. This product meets all of the limitations of the broadest claim pending in the above-captioned application (claim 78).

d. Before 3M's publication and introduction of the new filtering face mask product referred to in paragraphs 4.a and 4.b, it is my understanding and recollection, that essentially all previous commercial filtering face mask products had used an exhalation valve that had a centrally-mounted flap. Known valves that had centrally-mounted flaps

mainly had a circular flap member that was mounted to a valve seat through a central stake or button. These valves are commonly referred to in the art as "button-style" valves and had been used on 3M commercial filtering face masks for approximately 13 years before 3M's original filing date of the flapper-style valve of claim 78. Examples of button-style valves are shown in U.K. Patent Application 2,072,516A (Fig. 3) published 1981, U.S. Patent 2,895,472 (Fig. 5) published 1950, U.S. Patent 2,230,770 (Figs. 13-14, 27-29) published 1940, and U.S. Patent 4,630,604 (Figs. 1, 2 and 4-5) published 1986. Another centrally mounted valve --- although not nearly as common --- had been (and continues to be) sold by OH&ESD in Europe and is described in U.S. Patent 4,934,362 to Braun. This latter product is not referred to as a button-style valve. But the flap is centrally-mounted to the valve seat by a central bridge.

e. In 1995, Racal Health & Safety introduced in the United States a filtering mask that had a flapper-style valve. This new Racal mask had an exhalation valve that was similar to the structure and function of the flapper valve product that was previously published and introduced by OH&ESD and claimed in the above-caption application. A sample of this product is attached to this Affidavit as Exhibit B. This valve is also shown and described in Racal's U.S. Patent No. 5,687,767. Like the invention claimed in the present application, the Racal product has an exhalation valve that includes a valve seat and a single flexible flap. The valve seat has an orifice, a seal surface surrounding the orifice, and a flap retaining surface. The exhalation valve also has a single flexible flap that has a stationary portion and one free portion and a circumferential edge that includes stationary and free segments. The stationary segment of the circumferential edge is associated with the stationary portion of the flexible flap so as to remain in substantially the same position during an exhalation. The free segment of the circumferential edge is associated with the one free portion of the flexible flap so as to be movable during an exhalation. The free segment of the circumferential edge is disposed beneath the stationary segment when the valve is viewed from the front in an upright position.

f. Around approximately late 1998, Moldex Metric Inc. introduced in the United States a filtering face mask that also had a flapper-style valve. This new Moldex mask had an exhalation valve that was similar to the structure and function of the flapper valve

product that was previously published and introduced by OH&ESD and claimed in the above-captioned application. Moldex Metric sells this valve under the trademark Ventex™. A sample of this product is attached to this Affidavit as Exhibit C. This valve is also described in Moldex's U.S. Patent No. 6,047,698, filed August 20, 1998. Like the invention claimed in the present application, the Moldex product has an exhalation valve that includes a valve seat and a single flexible flap. The valve seat has an orifice, a seal surface surrounding the orifice, and a flap retaining surface. The exhalation valve also has a single flexible flap that has a stationary portion and one free portion and a circumferential edge that includes stationary and free segments. The stationary segment of the circumferential edge is associated with the stationary portion of the flexible flap so as to remain in substantially the same position during an exhalation. The free segment of the circumferential edge is associated with the one free portion of the flexible flap so as to be movable during an exhalation. The free segment of the circumferential edge is disposed beneath the stationary segment when the valve is viewed from the front in an upright position.

g. In approximately 1999, Ever Green Co. Ltd. of Korea introduced a filtration face mask product in that country, which mask was similar in structure and function to the respiratory product previously published and introduced by OH&ESD and claimed in the above-captioned application. A sample of their product is attached to this Affidavit as Exhibit D. Like the invention claimed in the present application, the Korean product has an exhalation valve that includes a valve seat and a single flexible flap. The valve seat has an orifice, a seal surface surrounding the orifice, and a flap retaining surface. The exhalation valve also has a single flexible flap that has a stationary portion and one free portion and a circumferential edge that includes stationary and free segments. The stationary segment of the circumferential edge is associated with the stationary portion of the flexible flap so as to remain in substantially the same position during an exhalation. The free segment of the circumferential edge is associated with the one free portion of the flexible flap so as to be movable during an exhalation. The free segment of the circumferential edge is disposed beneath the stationary segment when the valve is viewed from the front in an upright position.

-4-

h. In approximately March of 2000, Louis M. Gerson Company introduced in the United States a filtering face mask product that was similar in structure and function to the filtering face mask previously published and introduced by OH&ESD and claimed in the above-captioned application in paragraphs 4. a-c above). An example of this product is attached to this Affidavit as Exhibit E. Like the invention claimed in the present application, the Gerson product has an exhalation valve that includes a valve seat and a single flexible flap. The valve seat has an orifice, a seal surface surrounding the orifice, and a flap retaining surface. The exhalation valve also has a single flexible flap that has a stationary portion and one free portion and a circumferential edge that includes stationary and free segments. The stationary segment of the circumferential edge is associated with the stationary portion of the flexible flap so as to remain in substantially the same position during an exhalation. The free segment of the circumferential edge is associated with the one free portion of the flexible flap so as to be movable during an exhalation. The free segment of the circumferential edge is disposed beneath the stationary segment when the valve is viewed from the front in an upright position.

i. In approximately November of 2000, Survivair (division of Bacou USA Safety Inc.) introduced a filtering face mask product that had an exhalation valve similar in structure and function to the exhalation valve previously published and introduced by OH&ESD and claimed in the above-captioned application. A sample of this product is attached to this Affidavit as Exhibit F. Like the invention claimed in the present application, the Survivair product has an exhalation valve that includes a valve seat and a single flexible flap. The valve seat has an orifice, a seal surface surrounding the orifice, and a flap retaining surface. The exhalation valve also has a single flexible flap that has a stationary portion and one free portion and a circumferential edge that includes stationary and free segments. The stationary segment of the circumferential edge is associated with the stationary portion of the flexible flap so as to remain in substantially the same position during an exhalation. The free segment of the circumferential edge is associated with the one free portion of the flexible flap so as to be movable during an exhalation. The free segment of the circumferential edge is disposed beneath the stationary segment when the valve is viewed from the front in an upright position.

5. The public disclosure and introduction of the OH&ESD filtration face mask product of the above-captioned invention — followed closely by five competitive products that share the same new technology previously disclosed and claimed in the above-captioned application, and coupled with the fact that no previous filtering face mask product used this technology but primarily relied on centrally-mounted flap valve technology, particularly button-style valves — lead me to the firm conclusion that the technology first created by OH&ESD and claimed in the present application was copied by each of these competitors.

Brian S. McGinley

Subscribed and sworn to before me this 28th day of June, 2001.

Notary Public

SUSAN M. DACKO
NOTARY PUBLIC MINNESOTA
My Comm. Expires Jan. 31 2005

EVIDENCE APPENDIX

Exhibit B

Patent
Case No.: 48317US030

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:
DANIEL A. JAPUNTICH ET AL. Group Art Unit: 3761
Serial No.: 08/240,877
Filed: May 11, 1994 Examiner: A. Lewis
For: UNIDIRECTIONAL FLUID VALVE

DECLARATION OF JOHN L. BOWERS

I, John L. Bowers, state as follows:

2. I have been working in the respiratory field for about the past 15 years and am very familiar with the art pertaining to personal respiratory protection devices, including filtering face masks that are worn over the nose and mouth of a person and that use an exhalation valve to purge warm, moist, exhaled air from the mask interior.

3. I hold two U.S. patents in the respiratory field, including U.S. Patent 5,687,767 to Bowers, originally assigned to Racal Health & Safety Limited, England. This patent describes a unidirectional flapper style fluid valve that is useful as an exhalation valve on a filtering face mask.

4. I am familiar with the subject matter of the above-captioned application.

5. I used to be an employee at Racal Health & Safety Limited prior to the acquisition of its assets by 3M. I worked at Racal for 9 years and had the title of operations and technical manager. In that position, I was responsible for health and safety product development, particularly for respiratory masks.

6. I presently hold the position of site manager in the Occupational Health & Environmental Safety Products Division (OH&ESD) at the 3M Company, 12-16 Bristol Road, Greenford Middlesex, England. In this position I am responsible for the day to day operation of the manufacturing and distribution centers for powered and supplied air respirators.

7. While working at Racal, I was assigned the responsibility to develop a new exhalation valve for its respiratory masks. Racal had a number of customer requests for a mask

EXHIBIT B

Application No.: 09/678580 Case No.: 48317US030

that had an exhalation valve to purge warm, moist air from the mask interior. In considering candidates for exhalation valves on our respiratory products, I initially looked at conventional button-style valves. These valves, however, were not selected for widespread commercialization of Racal face masks because the cracking pressure required to open the button-style valve was found to be relatively high. I found that the central pivoting point created an undesirably higher opening force.

8. As part of the process for designing a new valve, I examined the exhalation valve that was recently commercialized by 3M. This valve is described in U.S. Patent 5,325,892 to Japuntich et al. I not only examined an actual commercial embodiment of the 3M valve, but I also carefully reviewed the disclosure of the '892 3M patent.

9. My evaluation of the 3M valve showed a product that had better performance than the conventional button-style valves. This evaluation led me in pursuit of developing a flapper-style valve similar to the 3M valve. The valve that was ultimately designed by me for Racal was the flapper-style unidirectional fluid valve that is shown in U.S. Patent 5,687,767 to Bowers; and a sample of which is attached to this Declaration as Exhibit G. I sought to design a valve that would avoid infringement of the issued 3M '892 patent and would be patentable over its disclosure. The filtering face mask that was developed, which employed the new Racal valve that I developed, did possess some features similar to the 3M valve and borrowed technology learned from the 3M valve. In particular, I designed the exhalation valve for Racal so that the flexible flap of the Racal valve was secured non-centrally relative to the orifice and had a free portion that was pressed against the seal surface when a wearer was neither inhaling nor exhaling, and the flap had a curvature in the free portion when viewed from the side elevation in a closed position (although the Racal valve that I designed was also made to have a transverse curvature). The flap was also designed to have stationary and free portions with a circumferential or peripheral edge that had stationary and free segments, respectively. The flap was secured to the valve seat at the flap-retaining surface closer to the stationary segment of the peripheral edge than to the free segment. Other than the transverse curvature, the features described in the three previous sentences were present in the 3M valve and were discovered from my examination of the 3M product and the published '892 patent. The Racal valve thus was able

to remain closed under neutral conditions under any orientation, like the IM valve, to prevent the inflow of contaminants and was also able to open under a relatively small exhalation force.

10. I have also read U.K. Patent Application GB 2072516 to Simpson et al. (Simpson) and U.S. Patent 3,191,618 to McKim, and I do not believe that the combination of Simpson and McKim would have led a person of ordinary skill in the art to the present invention. In my view, the McKim patent is not pertinent to the subject matter sought to be patented in the above-captioned U.S. Patent Application Serial No. 08/240,877 and is not pertinent to the subject matter taught in Simpson.

11. My review of the McKim patent shows a curved heat reed valve that is designed for use in a high-speed engine, which could turn at speeds as possibly as high as 10,000 or 12,000 revolutions per minute (rpm). The reed valve described in McKim is indicated to be particularly suited for a high speed operation where opening and closing forces are large. McKim states these forces can cause the valve to bounce (an apparent elastic recoil from impact). The stated goals in McKim are full and rapid opening, quick and complete closing, and eliminating float and bounce.

12. The field of the above-captioned '877 invention pertains to a filtering face mask that employs an exhalation valve. A filtering face mask is worn over the nose and mouth of a person for filtering contaminants that may be present in the ambient air. Filtering face masks commonly employ exhalation valves to allow warm, moist, exhaled air to be rapidly purged from the mask interior. The exhalation valves are used to improve wearer comfort. These valves generally operate at normal room temperatures and pressures.

13. The field of endeavor for filtering face mask is very different from the field of endeavor of a reed valve that is used in a two-cycle engine. Exhalation valves for respirators operate under very different conditions from valves that are used in two-cycle engines and require notably different design parameters. The valve that is described in McKim has very rapid opening and closing requirements (thousands of openings and closings per minute) and operates under temperatures and pressures that differ substantially from the requirements of exhalation valves, which open and close under the much slower pace of a wearer's breathing and under temperatures and pressures that tend to vary only from the ambient to that exhibited by the wearer's exhaled air. Thus, persons of ordinary skill in the field of designing filtering face

ruskin, to the best of my knowledge and experience, do not find valves for two-cycle engines to be in their field of endeavor and therefore do not consult documents that describe valves for these engines when developing new respiratory products.

14. In exhalation valves for filtering face masks, the speeds for opening and closing is not a primary design parameter. There is no incumbent need to rapidly fill or exhaust a combustion chamber. Further, under the airflows and pressure drops that are encountered in a filtering face mask, "bounce or float" is not an occurring event or a problem that investigators in the exhalation valve art need to deal with. Investigators who design exhalation valves for filtering face masks seek to produce exhaust valves that remain closed between breaths and that minimize the force or pressure needed to open the valve from its normally closed position. This particular design goal is not compatible with or comparable to fast-closing valves that require high forces for rapidly opening and closing. Exhalation valves tend to open and close at the rate of a person's breathing, which is about 20 to 60 cycles per minute. In contrast, the McKim valve is designed to operate at speeds as high as 10,000 to 12,000 revolutions per minute. The flow volumes and flap stiffness are orders of magnitude higher for valves that are used in combustion engines as opposed to valves that are used on respiratory masks. For these reasons, a person of ordinary skill in the filtering face mask art would not, in my view, have found the McKim patent to be reasonably pertinent to the problems that are encountered in the development of an exhalation valve for a filtering face mask. McKim would not be a reference that would have logically commended itself to the attention of persons of ordinary skill in developing new exhalation valves for filtering face masks. I have not, nor have I witnessed, anyone who is skilled in the field of developing filtering face masks, look at the art of valves for two-cycle engines for solutions to problems confronted by them in the exhalation valve art.

15. My review of the Simpson document reveals a flapper-style valve 13 in Fig. 2, which would not have its "flexible circular flap member 15" pressed against the valve's seal surface when a wearer of the mask is neither inhaling nor exhaling. The aligned relationship between the flap retaining surface and the seal surface and their relative positioning would not cause Simpson's flap 15 to be pressed against the valve's seal surface. At best the flap 15 would rest flush against the seal surface as a result of its securement at the flap retaining surface. The Simpson valve 13 therefore could allow for the influx of contaminants into the mask interior

when, for example, a wearer tilts their head downwards and allows gravity to draw the flap away from the seal surface.

To The Simpson product also has the valve located on the upper portion 1 of the pouch-shaped mask. This has the disadvantage that the warm moist exhaled air may be directed towards the eyes, causing misting of the eyewear. And Simpson's Fig 3 valve cannot be positioned on the underside of the mask because the flap 15 would droop away from contact with the valve seat, causing the valve to leak.

The undersigned petitioner declares further that all statements made herein of his own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issuing thereon.

Dated this 16th day of December, 2004.

John L. Bowers

Witness

Witness

START MILLER

RELATED PROCEEDINGS APPENDIX

None.